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10/719,851	11/24/2003	Alison Lewey	45317/043128	2951
30472 7590 05/02/2008 ANTHONY D. PELLEGRINI RUDMAN & WINCHELL, LLC			EXAMINER	
84 HARLOW STREET			LEVY, NEIL 8	
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## Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

### Application No. Applicant(s) 10/719.851 LEWEY, ALISON Office Action Summary Examiner Art Unit NEIL LEVY 1615 -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS. WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). Status 1) Responsive to communication(s) filed on 12 February 2008. 2a) This action is FINAL. 2b) This action is non-final. 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. Disposition of Claims 4) Claim(s) 3.4 and 6-19 is/are pending in the application. 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration. 5) Claim(s) \_\_\_\_\_ is/are allowed. 6) Claim(s) 3.4 and 6-19 is/are rejected. 7) Claim(s) is/are objected to. 8) Claim(s) 3.4.6-19 are subject to restriction and/or election requirement. Application Papers 9) The specification is objected to by the Examiner. 10) The drawing(s) filed on is/are; a) accepted or b) objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. Priority under 35 U.S.C. § 119 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some \* c) None of: Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). \* See the attached detailed Office action for a list of the certified copies not received. Attachment(s) 1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413) Paper No(s)/Mail Date.

Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO/S6/08) Paper No(s)/Mail Date \_

Notice of Informal Patent Application

6) Other:

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#### DETAILED ACTION

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

#### Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 3,4,6-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Language is indefinite, as "comprising" and comprised re-open the consisting terminology. Consequently, No weight is given to the consisting terminology.

Claims 16-19 fail to define & limit the insect repellent composition, because the weight % of claims 16-19 is open to interpretation. They may be of the active, or inactive, & still permit of other organic agents of both or either active or inactive, as recited in claim 4.

We fail to find sufficient support for the non-insecticidal—each of the ingredients (perhaps not wheat qerm oil) are in fact insecticidal to some insects.

Thus, the rejections of record have been maintained.

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Claims 3,4,6-19 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. At issue is the non-insecticidal statement.

The factors to be considered in determining whether a disclosure meets the enablement requirement of 38 U. S. C. 112, the first paragraph have been described inn re Wands, 8 USPQ2D 1400 (Fed Cir. 1988). Among these factors are (1) the nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims. (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary. When the above factors are weighed, it is the examiner's position that instant disclosure fails to meet the enablement requirement for the following reasons:

<sup>(1)</sup> The nature of the invention: claims are to unqualified repellant, non-insecticidal agents,

<sup>(2)</sup> The state of the prior art shows the use of these compounds are in fact both insecticidal & repellant.

<sup>(3)</sup> The relative skill of those in the art. The relative skill of those in the art is high.

<sup>(4)</sup> The predictability or unpredictability of the art. The unpredictability of the art is very high.

<sup>(5)</sup> The breadth of the claims. The claims are very broad, as the claimed % have no basis specified-whether of the active or inactive components, total composition, or some other aspect is not identified in claims.

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(6) The amount of direction or guidance presented. There is none dealing with pesticidal or insecticidal effects, or lack thereof, of any of the over 600000 insect species.

- (7) The presence or absence or working examples. There are none showing death of pests or lack thereof.
- (8) The quantity of experimentation necessary extensive-there is requirement for testing numerous species, to determine if adverse effects follow contact with the claimed compositions.

The specification provides no data showing that over a reasonable time (2-3 days), following biting or repelled mosquitoes (the only test animal reported) no adverse effects or deaths resulted.

The following patents show the instant compounds to be insecticidal, contrary to the statement attorney points to in the specification;

BESSETTE us006974584b2  $\,$  , at col. L6, lines 20-30 shows thyme oil insecticidal to mosquitoes.

WINDSOR US 20060276339A1 ,@ p. 29 & 31 shows peppermint & thyme insecticidal.

<code>HIROMOTO</code> us007019036b2 , @ Col. 2 shows lemongrass oil , rosemary oil thyme oil, geranium oil & soybean oil as pesticidal.

LEWIS US 20060008486A1 @ col. 13, [0030 & 0038] show peppermint, rosemary, soybean geranium & lemongrass oil as pesticidal.

Thus, the rejections of record are maintained.

Claim Rejections - 35 USC § 102 Claim Rejections - 35 USC § 103

Claim 3 stands rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over BESSETTE-6974584.

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Repelling insects from skin with safe compositions (column 2, lines 9-16) of (column 2, lines 45+) essential oils and carriers (the instant inactives). Oils are at column 3, lines 14-33 and D at column 7. Solvents, soy bean oil, are at column 4, line 55+.

Claims 3, 4, 6, 8,9,12,14,16 and 18 stand rejected under 35 U.S.C. 102(a & e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over..KEEN US 2003/0198696

This application-publication has a valid priority date to 10/19/2000, and also was published prior to applicant's filing date

The instant compositions are fish oil or vegetable oils, the instant inactives and emulsifiers (claim 1 and b, with instant actives (claim 2) at instant % (1-99%) claim 8 and mixed with carrier at 1-50% (claim 15). Claim 18 specifies repellent effects on insects.

Claim3, 4, 6,8,9,12,14,16 & 18 stand rejected under 35 U.S.C. 103(a) as being unpatentable over KAHAZAN-Enache US 2003/0175369and Keen- us 2003/0198696 in view of Bessette et al –US 20030194454

KAHAZAN- Enache teach GRAS essential oils as insect repellents are well known [0014, 0016] and those of the instant [0022] at 0.1-45% [0026] with vegetable oils Table 1, soy is not specified. KEEN shows these ingredients. With lemon grass oil, and soy bean oil are safe pesticidal alternatives. Thus, use of soy oil as KHAZAN teaches vegetable oil and added lemon grass and other oils of KEEN would increase the range of activity of the repellent compositions to more than just moths.

BESSETTE also shows the instant [0060] essential oils to be desirable as insect repellents [0066] at 5-99% inert carriers, of soy oil [0068]. The oils are seen as 0.0001-10% each [0075].

Khazan-Enache & Keen show the instant invention, but not specifically all the oils & vehicles/solvents/added organics. Added oils are shown by the secondary references, providing additional & alternative essential oils & soy bean oil.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made, desiring to utilize GRAS compositions, to use those well known in the art, as exemplified by the primary references, with selection of the equivalent OILS at concentration effective to control pests.

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All the critical elements of the instant invention are disclosed. The amounts and proportions of each ingredient are result effective parameters chosen to obtain the desired effects. It would be obvious to vary the form of each ingredient to optimize the effect desired, depending upon the particular pest species and crop interest, reduction of toxicity, cost minimization, enhanced, and prolonged, or synergistic effects.

Applicant has not provided any objective evidence of criticality, non-obvious or unexpected results that the administration of the particular ingredients' or concentrations provides any greater or different level of prior art expectation as claimed, and the use of ingredient for the functionality for which they are known to be used is not a basis for patentability.

The instant invention provides well known old art recognized compounds, with well known art recognized effects, applied by well known methods to achieve control over mollusks as is well known in the art.

Claims 3,4,6 -19 stand rejected under 35 U.S.C. 103(a) as being unpatentable over ROLF US 2004/0071757 in view of BESSETTE et al. & Culpepper '95

@ Rolf, See [0073] the instant essential oils, as compositions of mixtures with inert organics-polymers, acids, lecithin, alcohols [0102] at 1-70% [0103] and with fish oil, mineral oil [0130]. The oil are seen at 1-5% each (Examples) and serve as antimicrobials. BESSETTE show [0054] antimicrobials include the instant compositions [see above) with soy bean carrier.

Culpepper is cited to show the advantage of wheat oil(p. 270,271)- it is useful to smooth skin, & wheat bran meal is helpful against venoumous creatures. Absent any showing of objective evidence of nonobvious or unexpected results, adding Culpeppers wheat oils to the cited compositions can only enhance their effectiveness & aesthetic properties when applied to skin.

Applicant's arguments filed 212/08 have been fully considered but they are not persuasive. Arguments area based on a presumed bad date, it isn't; & all references are to insecticidal compositions; so are applicants- the same compositions are shown in the prior art, or are obvious.

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Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NEIL LEVY whose telephone number is 571-272-0619. The examiner can normally be reached on Tuesday-Friday, 7 AM to 5:30 PM EST..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, MICHAEL WOODWARD can be reached on 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/NEIL LEVY/ Primary Examiner, Art Unit 1615